

REMARKS

In an Office Action dated October 4, 2006, claims 1-22, all of the claims of the above-identified patent application, were rejected. In view of the above amendments and the following Remarks, Applicants respectfully request reconsideration of this application and allowance of the claims, as amended.

All of the claims have been rejected under 35 USC § 103(a) as being unpatentable over various combinations of Geistlich et al. US Patent No. 5,837,278 (Geistlich '278), Shimizu U.S. Patent No. 6,090,117, the abstracts of Hentz et al. and Rosen et al., Stensaas et al. US Patent No. 4,778,467 and/or Humes U.S. Patent No. 5,429,938. These rejections are respectfully traversed.

All of the claims of the present application require that the tube be formed of a single sheet of resorbable collagen sidewall material.

Geistlich '278 discloses a collagen membrane for use in bone regeneration around the root of a tooth. Geistlich '278 contains no suggestion whatsoever of a nerve regeneration tube for reconnecting nerve ends.

Shimizu discloses an artificial tube for nerve regeneration which always is formed of at least three sheets. The Shimizu reference fails to disclose or suggest a nerve regeneration tube formed of a single sheet of resorbable collagen sidewall material.

Hentz et al. and Rosen et al. both disclose nerve repair wherein a membrane of hypoantigenic collagen is wrapped around the nerve.

Stensaas et al. discloses a prosthesis for nerve regeneration which is made of a fluid-impermeable layer composed of silicone, rubber, polyurethane, teflon or nitrocellulose.

Humes '938 does not even relate to nerve regeneration tubes. Instead, Humes '938 is directed toward a renal tubule tissue system prepared by a process in which adult kidney cells are cultured in a culture medium which may contain Type I collagen and/or Type IV collagen. This reference fails to supply any of the above-noted deficiencies of the other applied references.

No combination of the above references suggests the invention as presently claimed. In fact, the prior art as a whole leads away from the present invention.

The Shimizu reference has a priority date of November 20, 1996, almost a year and a half after the July 13, 1995 PCT publication date corresponding to Geistlich '278. Shimizu also was filed more than 3 years after the 1993 publication date of Hentz et al., more than 7 years after the 1989 publication date of Rosen et al. and almost 1-1/2 years after the publication of Humes '938. Shimizu was aware of prior use of collagen tubes for nerve regeneration, and of the problems previously associated therewith.

Persons of ordinary skill in the art, looking at all of the teachings of the prior art, would not have expected the membrane disclosed in Geistlich '278 to work as a nerve regeneration tube as presently claimed. This is because the prior art itself casts doubt on the efficacy of utilizing collagen tubes for nerve regeneration. This is made clear in the Shimizu reference, which states:

Although artificial tubes for nerve which comprise collagen tubes in which collagen fibers on which laminin and fibronectin are coated are filled (Tong, X., et al., Brain Research 663: 155-162 (1994)) have recently been attempted, since the collagen tubes are unable to remain without being broken down until the nerve is regenerated to an adequate length, satisfactory results have not been obtained. (Column 1, last full paragraph, emphasis added).

In view of the above, persons of ordinary skill in the art, taking into consideration all of the teachings of the prior art, could not have predicted the efficacy of utilizing a single sheet of the Geistlich '278 membrane for a nerve regeneration tube. Instead, because of the prior art problems associated with collagen tubes as reported in Shimizu, persons of ordinary skill in the art would not have expected the single sheet collagen tube of the present invention to work, but instead would have expected the necessity of utilizing multiple sheets as in Shimizu.

The office action states:

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the single sheet collagen material of the '278 patent to make a nerve regeneration tube out of collagen as taught by Shimizu because Shimizu employs at least three sheets of collagen to produce his nerve regeneration tube and by using a single sheet of collagen with the attractive features (one side smooth and inhibits cell permeation, the other side fibrous to promote biological regrowth) taught by the '278 patent, a simpler nerve regeneration tube can be produced that uses less material (single sheet as opposed to at least three sheets of collagen), is quicker and easier to produce, and would have the further advantage of economic savings due to lowered costs of production by reducing the need for at least three sheets of collagen to a single sheet of collagen.

Clearly, the above is the Examiner's suggestion made with hindsight knowledge of the present invention, and is not a suggestion in the prior art. Instead, the prior art leads away from the invention for the reasons outlined above.

In view of the above amendments and remarks, withdrawal of the rejections based on the references discussed above is respectfully requested.

Applicants submit that the present application is now in condition for allowance.
Reconsideration and favorable action are earnestly requested.

Respectfully submitted,

By



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